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| 10/569,585 | 03/27/2006 | Kazukiyo Hemmi | F-8991 | 5942 |
| 28107 7590 05/08/2009 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168 | | | | |
| EXAMINER | | | | |
| MINSKEY, JACOB T | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/569,585

Applicant(s)

HEMMI ET AL.

Examiner

JACOB T. MINSKEY

Art Unit

1791

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Claims 1-8 have been amended in order to broaden the language of the claims.
2. Applicant's arguments filed 03/02/2009 have been fully considered but they are not persuasive.
3. Applicant argues that the anticipation rejection of claims 1, 3, 5, and 6 in view of Davis is incorrect because Davis does not teach each and every element of the claim. Applicant argues that Davis does not teach the limitation of "pushing in a portion of said substrate material" into the lateral arch of the patent's foot.
4. The Examiner respectfully disagrees. As stated in the previous Office Action, and presented in the Applicant's Arguments, Davis teaches "[t]he softened thermoplastic material is then shaped and detailed to the bottom of a user's foot ... [and] is molded by hand to all the curves and dimensions of the foot" (page 8 of Applicant's response). Davis further teaches molding by hand to all the curves and dimension of the foot from around the heel up to and including the metatarsal arch [0038].
5. The Examiner disagrees with the Applicant's position that the act of molding the material to the bottom of the patent's foot is a passive activity that does not include the act of "pushing in" of the material. The act of molding the material to the bottom of a patent's foot (especially any of the arches) would require that material is pushed into the cavities. Davis explicitly teaches this through the use of the Doctor's hands to "mold by hand to all the curves and dimension of the foot from around the heel up to and

including the metatarsal arch" [0038]. It is the Examiner's position that force is required to push the material into position in order to mold all of the curves and dimensions of the patent's foot.

6. Applicant further traversed the obviousness rejection of claim 2 of Davis in view of Bivans. Applicant argues that Bivans does not overcome the arguments of claim 1 as discussed above. Additionally, Applicant argues that Bivans teaches the use of a spatula to fill cavities, and that this is not the same field of endeavor of using a spatula to push in thermoplastic resin.

7. The Examiner respectfully disagrees. The act of filling a cavity with a spatula is analogous to the act of using a spatula to "push in" material into an arch. The active methods steps for both actions are the same and would have been obvious to one of ordinary skill in the art to combine. Bivans teaches shaping of a melted wax to conform to the cavities of a patents body, and it the Examiner's position that the melted wax would behave in a similar manner to the heated and pliable thermoplastic material claimed in the instant application.

8. Applicant further traverses the anticipation rejection of claim 4 of Davis in view of Brown. Applicant argues that Brown does not overcome the arguments of claim 1 as discussed above, and additionally does not teach the claimed "depression forming members."

9. The Examiner respectfully disagrees. The splints that are added in the Brown reference are added to the foot before the casting of the foot in plaster. These splints will have to form depressions in the plaster as the foot is being molded. The splints are

laid for strength and support of the cast, but directly read on the claimed limitations of a depression forming member that is attached to the foot before molding.

10. Applicant further traverses the anticipation rejection of claim 7 of Davis in view of Geer. Applicant argues that Geer does not overcome the arguments of claim 1 as discussed above (see arguments of claim 1 above).

11. The previously made rejections are presented in the following section:

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 3, 5, 6, and 8 are rejected under 35 U.S.C. 102(e) as being Anticipated by Davis et al, US patent publication 2006/0086004 A1.

14. Regarding claim 1, Davis et al teach a sole plate (foot support, see abstract) production method comprising the steps of heating a sole-plate substrate material made of thermoplastic resin (microwave, hot water, or induction [0038]), pressing said heated substrate material relative to a foot sole of a human to prepare a sole-plate substrate having a shape corresponding to a sole arch of said foot sole (shaped and detailed to

the bottom of users foot [0038] and molded by hand... including the metatarsal arch [0038]), and producing a sole plate using said obtained substrate, wherein:
said step of pressing the heated substrate material relative to the foot sole (shaped and detailed to the bottom of users foot [0038]) includes pushing in a portion of said substrate material corresponding to an apex of a lateral arch of said sole arch to allow said substrate to be formed with a convex portion corresponding to the apex of said lateral arch (molded by hand to all the curves and dimension of the foot from around the heel up to and including the metatarsal arch [0038]).

15. Regarding claim 3, Davis remains as applied in claim 1 and further teaches the step of forming a slit (recesses, items 30, 30a and 30b [0031] see figure 4) in said convex portion of said substrate to extend in a longitudinal direction of said substrate and have an open end at a toe-side end of said substrate (see figure 4).

16. Regarding claim 5, Davis remains as applied in claim 1 and further teaches that said step of pressing the heated substrate material relative to the foot sole includes pressing opposite side portions of said substrate material, respectively, onto opposite side regions of said foot sole to extend upward so as to allow said substrate to be formed with a pair of side supports (inner and outer lateral sides, items 22 and 23 [0029] see figures 1 and 2 and molded by hand to all the curves and dimensions of the foot [0038]).

17. Regarding claim 6, Davis remains as applied in claim 5 and further teaches that said side supports are formed in only a portion of said substrate which extends from a position corresponding to respective shafts of first and fifth metatarsal bones of the foot

sole toward a heel end of said substrate (preferably the foot support extends from the heel to just short of the ball of the foot, including the metatarsal arch [0011] see figure 2).

18. Regarding claim 8, Davis remains as applied in claim 1 and further teaches that said substrate material is pre-formed prior to heating (precut [0037]) to have an outside dimension capable of being formed directly into a final shape of said substrate (as described in [0037]).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al, US patent publication 2006/0086004 A1 in view of Bivans, USP 3,444,291.

23. Regarding claim 2, Davis remains as applied in claim 1 and while Davis teaches applying the substrate to the lateral arch by use of the practitioner's hand, Davis does not teach the step of providing a spatula having a convexly-curved end, wherein said step of pressing the heated substrate material relative to the foot sole includes bringing said end of said spatula into contact with the portion of said substrate material corresponding to an apex of a lateral arch of said sole arch to push in said portion so as to allow said substrate to be formed with a convex portion corresponding to the apex of said lateral arch.

24. It is well known at the time of the invention to use a spatula to push the substrate material into position. In solving the same problem of applying material to cavities on a patient's body, Bivans teaches the filling materials into cavities in the skin using "any form of suitable mechanical aid such as a spatula, wood stick, etc (column 3 lines 33-37) for the benefit of consistency, sanitation, and being able to smooth the material to completely fit the contours of the patient's body.

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Bivans's use of a spatula applicator in the Davis method for the benefit of consistency, sanitation, and being able to smooth the material to completely fit the contours of the patient's body.

26. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al, US patent publication 2006/0086004 A1 in view of Brown, USP 3,995,002.

27. Regarding claim 4, Davis remains as applied in claim 1 but does not teach the step of attaching a depression forming member onto a long plantar ligament region of said sole arch before said step of pressing the heated substrate material relative to the foot sole, and then pressing the heated substrate material relative to the foot sole to allow said substrate to be formed with a depression corresponding to said depression forming member.

28. In the same field of endeavor of casting orthotics, Brown teaches the step of attaching a depression forming member (splints, column 9 line 6) onto a long plantar ligament region of said sole arch (extends over first and fifth M.P. joints to navicular, column 9 lines 8-9) before said step of pressing the heated substrate material relative to the foot sole (a positive cast can be made, column 9 lines 21-22), and then pressing the heated substrate material relative to the foot sole to allow said substrate to be formed with a depression corresponding to said depression forming member (inherent from description in column 9 lines 6-23) for the benefit of controlling the decompression of the soft tissue and midtarsal joints in the functional fabricated cast (column 8 lines 46-68).

29. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Browns use of a splint in the Davis method for the benefit of controlling the decompression of the soft tissue and midtarsal joints in the functional fabricated cast.

30. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al, US patent publication 2006/0086004 A1 in view of Geer et al, USP 7,059,067 B2.

31. Regarding claim 7, Davis remains as applied in claim 5, but does not teach the step of forming a notch in each of said side supports at a position closer to a toe-side end of said substrate relative to an immovable joint region of said foot sole.

32. In the same field of endeavor of forming orthotics, Geer et al teach the step of forming a notch (flex notch, item 606 figure 6 and item 48 column 11 lines 15-29) each of said side supports at a position closer to a toe-side (forefoot area, column 12 line 51) end of said substrate relative to an immovable joint region of said foot sole (see column 12 lines 49-58) for the benefit of providing flexibility to the orthotic to facilitate movement and rotation and generate comfort for the patient.

33. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Geer's use of a flex notch in the Davis method for the benefit of providing flexibility to the orthotic to facilitate movement and rotation and generate comfort for the patient.

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JACOB T. MINSKEY** whose telephone number is **(571)270-7003**. The examiner can normally be reached on **Monday to Friday 7:30-5:00 EST**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on **571-272-1189**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JTM

/Eric Hug/
Primary Examiner, Art Unit 1791